UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL No. 2804**
	)	
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	
Track One Cases	)	**Judge Dan A. Polster**
	)	

BRIEF IN SUPPORT OF HBC SERVICE COMPANY'S MOTION FOR SUMMARY JUDGMENT

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A division of Giant Eagle, Inc. ("Giant Eagle"), Defendant HBC Service Company ("HBC") was one of the last Pharmacy Defendants dragged into this litigation after discovery had already begun.[1] Yet despite their delay, Plaintiffs did not include a single allegation of wrongdoing by Giant Eagle in the Second Amended Complaint. Now, after massive discovery, it is clear Plaintiffs sued Giant Eagle as an afterthought: Plaintiffs have failed to identify a single "inappropriate" prescription of a medication distributed by Giant Eagle and Plaintiffs' army of experts offer no testimony that Giant Eagle breached any duty of care or violated any Drug Enforcement Agency ("DEA") regulation. Giant Eagle is plainly a victim of Plaintiffs' efforts to name as many defendants as possible first, and ask questions later. The time has come for this Court to dismiss Giant Eagle from this case.

I. STATEMENT OF UNDISPUTED FACTS

Giant Eagle, a Pittsburgh-based family-owned supermarket chain, offers a wide array of products, including prescription and over the counter medication sold through its in-store pharmacies. From November 2009 through January 2016, HBC, Giant Eagle's 305,000 square foot warehouse distribution center located in Washington, Pennsylvania (the "HBC Warehouse"), supplied Giant Eagle in-store pharmacies—and only Giant Eagle in-store pharmacies—with Schedule III, IV, and V controlled substances. Ex. 1 at 121:24-125:13.[2] In January 2016, Giant Eagle opened a new warehouse that was a separately licensed unincorporated division known as Giant Eagle Rx Distribution Center ("GERXDC"), which started distributing Schedule II-V controlled substances to Giant Eagle Pharmacies in March 2016. Plaintiffs' allegations and

[1] Plaintiffs added HBC as a defendant in their May 18, 2018 Second Amended Complaint. *See* Dkt. Nos. 476 n.2 and 477 n.2. HBC is a general distribution warehouse and unincorporated operating division of Giant Eagle. As set forth in *Pharmacy Defendants' Memorandum of Law in Support of Their Motion for Summary Judgment Based on the Statutes of Limitations*, Dkt. No. 1691, the statutes of limitations preclude any relief for Giant Eagle distributions before May 18, 2014. Unless otherwise indicated, references to Giant Eagle include HBC.

[2] Citations to "Ex." refer to exhibits to the Declaration of Joshua A. Kobrin in Support of Defendant HBC Service Company's Motion for Summary Judgment, dated June 28, 2019, and filed contemporaneously with this Brief.

discovery efforts in this case have focused on Giant Eagle's HBC facility, which, from November 2009 until September 2014, distributed only *one* product that is relevant to this litigation: generic hydrocodone combination products, also known as HCPs.[3] *Id.*

A. The Controlled Substances Act and the "Security Requirement"

Congress passed the Controlled Substances Act (the "CSA") in 1972 to consolidate federal drug policy relating to the manufacture, importation, possession, use, and distribution of certain drugs. This litigation has focused on the "Security Requirements" in Part 1301 of the CSA regulations, which instructs "all applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. §1301.71(a) (the "Security Regulation"); *see also* Ex. 2 at 4. The Security Regulation lists numerous factors that the DEA may consider when assessing the registrant's compliance with the Security Requirements, including the (1) "type of activity conducted," (2) "type and form of controlled substances handled," (3) "quantity of controlled substances handled," (4) the registrant's internal controls, and (5) numerous factors related to warehouse security. *Id.* §1301.71(b)(1)-(14).

In this litigation, Plaintiffs' arguments have focused on DEA regulation 21 C.F.R. §1301.74(b), which instructs registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant" ("Suspicious Order Monitoring" or the "SOM" regulation). The SOM regulation is one component of the Security Regulation.

Because every registrant's circumstances are unique, the DEA has deliberately encouraged each registrant to review its own business model and customer base and design a SOM system that

[3] From October 2014 to March 2016, Giant Eagle did not distribute any opioids at issue, and instead relied on McKesson to supply all opioids at issue to Giant Eagle pharmacies.

fits its specific method of distribution.[4] Ex. 3 at 446:18-447:14, 179:22-180:15. The DEA also grants each registrant broad discretion over: (1) how, or whether, it documents its SOM procedures or due diligence, (2) how it conducts due diligence, and (3) how, or whether, it maintains SOM records. Ex. 4 at 251:17–252:18, 253:6–254:5; *see also* Ex. 3 at 103:6-16, 179:22–180:15; *cf. id.* 108:23–109:4, 180:7-22 (agreeing that the DEA does not require registrant's use a threshold system). For this reason, while the DEA reviews written policies and procedures, it also visits distribution facilities to ensure that registrants "are doing what they're saying" and are "actually detecting suspicious orders." Ex. 3 at 103:6–104:4; *see also id.* at 129:20–130:12, 131:15-23.

B. Giant Eagle complied with the Controlled Substances Act at all relevant times.

When Giant Eagle's HBC Warehouse distributed HCPs (November 2009 to September 2014), the DEA designated them a Schedule III controlled substance pursuant to the CSA.[5] 21 U.S.C. § 812 (b); 79 Fed. Reg. 163 (Aug. 22, 2014) (codified at 21 C.F.R. pt. 1308). In order to distribute HCPs, Giant Eagle developed comprehensive policies and procedures to ensure the HBC Warehouse complied with the CSA. *See* Ex. 1 at 162:24-163:11; *see also* Ex. 5 at 86:8-25. These procedures went beyond the letter and the spirit of the CSA and incorporated integrated controls at three levels of Giant Eagle's business: (1) the warehouse, (2) the pharmacies, and (3) corporate.

1. Policies and Procedures at the Warehouse

At the HBC warehouse, Giant Eagle sectioned off a DEA-approved 1,200 square foot cage to secure its inventory of Schedule III, IV and V controlled substances (the "CS Cage"). Ex. 2 at 7; Ex. 6. Giant Eagle also appointed a warehouse operations manager who oversaw distribution

[4] Encouraging individualized means of compliance, the regulation also provides that, "after evaluation of the overall security system and needs of the applicant or registrant," substantial compliance with the provisions that follow—§1301.72 through §1301.76—"may be deemed sufficient." §1301.71(b); *see also* Ex. 3 at 395:10–396:18 (DEA 30(b)(6) witness conceding that substantial compliance is sufficient).

[5] Schedule III controlled substances have a "potential abuse less than… schedules I and II." 21 U.S.C. § 812(b)(3)(A).

operations and ensured compliance with the CSA and DEA Regulations.[6] Ex. 7 at 13:6-10. The operations manager supervised a warehouse pharmacy manager, who was responsible for establishing and implementing policies and procedures in the pharmacy space and managed a select group of controlled substance "Pharmacy Pickers." Ex. 1 at 20:17-20, 31:9-24; Ex. 7 at 16:7-19. The Pharmacy Pickers had controlled access to the CS Cage, where they filled totes with inventory pursuant to orders from Giant Eagle pharmacies, which were, in turn, based upon legitimate prescriptions. Ex. 1 at 102:17-104:20, 129:22-133:16. To ensure verifiable accuracy, Giant Eagle equipped the Pharmacy Pickers with an electronic Vocollect communication and scanning system that guided the individual Pharmacy Picker's proper selection of products to fill individual orders, while other computerized systems kept real-time counts of the CS Cage inventory. Ex. 1 at 145:21-146-22.

Giant Eagle also conducted inventory counts of controlled substances in the CS Cage at least four to six (4-6) times a day to ensure that product was not missing or misplaced. Ex. 1 at 143:12-25 ("[W]e wanted to ensure the integrity of [our] inventory. But also it gives you an opportunity to catch anything that . . . may be amiss."). Giant Eagle encouraged the Pharmacy Pickers and the warehouse pharmacy manager—who were experienced pharmacy warehouse employees—to flag orders that were unusual or that might need additional follow-up or investigation because they deviated from the normal size, pattern, or frequency of orders from Giant Eagle pharmacies. *See* Ex. 1 at 90:8-91:7; Ex. 8 at 96:2-8.

In 2014, the DEA rescheduled HCPs from Schedule III to Schedule II controlled substances. On September 30, 2014, one week prior to the reschedule, HBC stopped distributing

[6] The HBC warehouse secured controlled substances in a locked cage made of 10 gauge steel mesh, equipped with an independent alarm system with motion sensors, automatic doors, and dozens of video cameras that allowed for web-based security of operations and points of ingress and egress. Ex. 6 at HBC_MDL00189107; Ex. 1 at 31:25-32:24; 36:4-15; 134:23-138:4. Access to the cage was strictly limited. Ex. 6 at HBC_MDL00189107; Ex. 8 at 276:17-279:5.

HCPs into the Counties. In March of 2016, GERXDC started distributing Schedule II-V controlled substances to Giant Eagle pharmacies after DEA inspection and approval of the facility. Ex. 1 at 174:21-175:18. All of the aforementioned controls—and additional enhancements (such as new monitoring software and the integration of controls with ordering programs)—apply equally to GERXDC.[7]

2. Policies and Procedures at Giant Eagle Pharmacies

Giant Eagle's pharmacies are on the front lines of ensuring prescriptions are properly filled and dispensed. *See generally* Ex. 8 at 281:9-293:2. For this reason, Giant Eagle supports its pharmacists by both (1) providing them with the medications they need to fill legitimate prescriptions and (2) giving them the authority to deny any prescription deemed, in the pharmacist's professional judgment, to be illegitimate.

In Ohio, a pharmacist is a medical professional who dispenses drugs to patients according to a prescription ordered by a physician or other clinician. Ohio Rev. Code § 3719.05.[8] As a medical professional, unless a pharmacist determines that a prescription is not legitimate, the pharmacist has an obligation to care for the patient. Ex. 11 at 225:7-226:15. In fact, a pharmacist may not modify a prescription for a Schedule II controlled substance unless he consults with and obtains the agreement of the prescriber. Ohio Admin. Code 4729-5-30.

With these obligations in mind, Giant Eagle has made clear that it *will* support its pharmacists' professional judgments should a pharmacist doubt the veracity or medical necessity of a prescription. Ex. 12 at ¶ 96; Ex. 9 at 244:4-25; *see also, e.g.*, Ex. 13. Giant Eagle also provides

[7] This Brief focuses on HBC because, despite receiving GERXDC documents and learning about GERXDC's distribution activities in discovery, Plaintiffs have asserted no claims of wrongdoing as to GERXDC and, throughout this litigation, have focused their attention on Giant Eagle's HBC warehouse operation.

[8] *See* Ohio Pharmacists Ass'n, *OPA Mission Statement, History, Code of Ethics*, Ohio Pharmacists Association, https://www.ohiopharmacists.org/aws/OPA/pt/sd/news_article/1696/_self/layout_details/false (last visited June 27, 2019).

its licensed pharmacists with training, policies, and procedures on everything from proper dispensing practices to "red flags" that indicate a potentially illegitimate prescription.[9] *See* Ex. 14 at 213:19-215:12 (explaining that Giant Eagle supplied every pharmacy with the DEA Pharmacist Manual, the Giant Eagle Controlled Substance Dispensing Guideline, and computer-based training on the Guidelines); *see also, e.g.*, Ex. 13; Ex. 15.[10] Giant Eagle Pharmacists in Ohio also utilize the OARRS System to verify prescriptions. Ex. 5 at 226:3-228:5; Ex. 14 at 213:19-215:12.[11]

To secure controlled substances, Giant Eagle Pharmacies keep every medication under lock and key, with exhaustive inventory checks, including (1) back counts of product at the point of dispensing; (2) daily inventories of controlled substances; (3) monthly narcotics audits, and (4) annual inventory counts for all controlled substances. Ex. 14 at 64:6-66:15, 225:19-226:14; Ex. 16 at 267:24-268:14. These controls exceed the DEA's requirements. Ex. 12 at ¶ 123.

Finally, Giant Eagle employs Pharmacy District Leaders or "PDLs." Each PDL oversees 29-33 Giant Eagle Pharmacies, investigating orders of interest, supervising pharmacy employees and their training, and conducting regular inspections of pharmacies to ensure compliance with all policies and procedures. Ex. 16 at 268:15-269:23; *see also* Ex. 5 at 232:13-233:19.

3. Policies and Procedures at Corporate

Giant Eagle's corporate office in Pittsburgh oversees the entire pharmaceutical operation from orders to distribution to pharmacy to patient. Ex. 17 at 18:14-20:8. The warehouse "had daily

[9] Ex. 9 at 244:4-25 ("You have to do your due diligence and make your individual determination based on the prescription, the prescribing pattern of the physician, the patient, to determine is this a – is it being used for legitimate use."); *see also* Ex. 10 at 38:10-39:4 ("[W]e have a process in place. You do your due diligence. You make a decision that way. If part of the due diligence says this guy doesn't need a script, he's a bad doctor, then send them on the way."); *see also id.* 158:5-159:5, 160:11-18.

[10] *See also* Ex. 5 at 226:3-228:1; Ex. 10 at 50:25-51:25 ("We have document control dispensing. In that document it lists the red flags, what to look for to do the due diligence and make that decision… the age, the distance, the distance they drive, the distance from the doctor to the pharmacy and the distance where they live and to the pharmacy. If they mention the drugs by the street names, Percs, Vics. Any kind of combination product, the trinities, the pain reliever, the muscle relaxer, those are usually a sign that calls might need to be made.").

[11] *See also* Ex. 10 at 159:13-160:18 (explaining scrutiny of scripts).

communications with the corporate team via phone and/or through… systems monitoring inventory and communicating [about] inbound/outbound shipments." Ex. 1 at 63:4-16. Corporate buyers placed orders to fill HBC's inventory and, like the Pharmacy Pickers at the warehouse, were responsible for identifying larger trends and deviations from the same.[12] Ex. 12 at ¶ 62.

Beginning in 2013, Giant Eagle incorporated a "threshold system" to provide another way to monitor controlled substance movement.[13] The threshold system created monthly ordering thresholds for products at Giant Eagle pharmacies. Ex. 18 at 114:12-117:22. Applying a threshold of three times the average monthly volume[14] for a given chemical GPI (the generic product indicator of the active ingredient) from the previous twelve months, the system flagged orders and sent an automatic email to an investigation team. Ex. 8 at 117:5-120:18. Members of the team investigated each of these "orders of interest" to ensure that they were legitimate and confirm that the ordering pharmacy was not facilitating any diversion.[15]

Ultimately, the threshold system merely supplemented the existing Giant Eagle system that had "adequate controls in place from the beginning." Ex. 11 at 177:22-184:23.[16] This is because *all* orders were (1) from Giant Eagle pharmacies and (2) based upon legitimate prescriptions.

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[12] *See also* Ex. 17 at 36:10-21; Ex. 5 at 142:11-143:10; Ex. 8 at 99:1-100:24 ("[S]uspicious orders would have been identified certainly from the warehouse, certainly folks in corporate that were – from the procurement team buying into the warehouse. They would know if there's any spike in pattern of product being demanded to be shipped to the warehouse."); *see also* Ex. 1 at 86:5-23 ("The corporate team had full visibility of [HBC Warehouse's] inventory at all times and could see if there was any fluctuation whatsoever.").

[13] Ex. 5 at 150:4-152:7; Ex. 9 at 171:16-172:14; Ex. 8 at 305:22-306:2 (HBC was under no obligation to utilize a threshold system, but did anyway "as one level of control").

[14] Ex. 8 at 120:19-122:21 ("[D]uring the due diligence to set the threshold, information was derived from the DEA published websites on a 3X threshold [] used for list chemicals, and that's where our 3X number was derived from.").

[15] *Id.*; Ex. 8 at 162:18-163:10 ("[E]very order that pops up of interest is investigated and either cleared or not"); Ex. 16 at 185:6-15 ("[W]e had daily reports based on stores that may have exceeded that threshold that we had set up, and if stores flagged on those reports, they were followed up on."), 214:3-216:24 (investigation process). Giant Eagle has constantly updated its threshold system, along with its overall SOM system, since the first iteration in 2013. *See e.g.*, Ex. 5 at 225:1-226:2 (explaining threshold system enhancements, including integration of the CSOS System and Supplylogix software); Ex. 16 at 235:3-238:7; Ex. 9 at 257:22-258:19 (discussing Giant Eagle's investment in new software and personnel).

[16] *See* Ex. 5 at 251:3-25; Ex. 18 at 136:13-24 ("This check was just an additional redundant check."); Ex. 8 at 296:7-25.

C. The DEA's Multiple Audits and Inspections of Giant Eagle's Controls

To obtain—and retain—its DEA license to distribute Schedule III-V controlled substances, Giant Eagle had to pass a thorough DEA pre-registration inspection and follow up inspections and audits. This provided the DEA with multiple opportunities to see how Giant Eagle's policies and procedures applied in practice. Ex. 3 at 129:20–130:12 (DEA witness, Prevoznik, explaining that DEA warehouse inspections allowed investigators to see how a registrants' SOM systems operated); *see also id.* at 103:6-104:4, 131:15-23.

When the DEA first visited HBC, Agents investigated security features and processes related to the CSA, as well as Giant Eagle's documentation of its procedures. *See* Ex. 5 at 86:8-25, 200:2-24. Following this inspection, the DEA concluded that HBC met the requirements in the CSA, and granted Giant Eagle the necessary approvals to distribute Schedule III, IV and V controlled substances from the HBC warehouse. *See id.*

After granting HBC its registration, the DEA conducted periodic inspections and audits of the HBC Warehouse. Ex. 16 at 259:11-23. Throughout all of these inspections and audits, the DEA never issued an order to show cause, never issued any citations, and never pursued any adverse actions.[17] *Id.*; Ex. 5 at 222:24-223:16; Ex. 14 at 60:3-61:3; Ex. 1 at 171:16-22.

This is because Giant Eagle has always complied with the Security Regulation in §1301.71 and the standards set forth in §§ 1301.72-76. Ex. 11 at 227:20-231:5; Ex. 2 at 2(E), 5-6 (Expert Greimel's opinion that Giant Eagle's system "complied with the DEA's standards in all relevant respects, especially considering that HBC was both a captive self-distributor and only distributed

[17] There were, of course, isolated incidents where Giant Eagle's anti-diversion systems caught breaches in the otherwise closed distribution system. The system caught a handful of warehouse employee thefts of non-opioid products. In those cases, Giant Eagle identified the offenders, promptly fired each, and used these instances as an opportunity to reevaluate and improve the internal controls. *See* Ex. 1 at 181:22–183:23; Ex. 14 at 106:11–107:4, 211:1–21. The systems also caught two suspicious orders. Both were orders from Pennsylvania pharmacies and both involved buprenorphine, a Schedule III opioid that is not part of this litigation. Ex. 9 at 206:3-24. Giant Eagle promptly reported both suspicious orders to the DEA and engaged in extensive investigations. *Id.*

Schedule III-V controlled substances"). Giant Eagle designed and implemented a system that was highly effective at preventing diversion for its particular captive distribution operation. This is particularly evident when one considers that:

- HBC's distribution of controlled substances into Summit and Cuyahoga Counties (the "Counties") was limited to: (a) Schedule III, IV, and V controlled substances, (b) only one relevant product (HCPs), and (c) the time period from November 2009 through September 30, 2014 (one week before the DEA reclassified HCPs from Schedule III to Schedule II).

- HBC and GERXDC registered as distributors of controlled substances, were approved by the DEA after thorough pre-registration inspections, and passed all subsequent inspections and audits en route to unblemished records of proper distribution.

- The ratio of controlled substance prescriptions to total prescriptions dispensed, for all Giant Eagle pharmacies in the Counties during the relevant time period was less than 10%.[18] *See* Ex. 12 at ¶ 76 & Ex. H.

- Giant Eagle never advertised or promoted opioid prescriptions.[19]

- Compared to its sales of other pharmaceutical products, Giant Eagle actually filled *fewer* opioid prescriptions than its overall market share would suggest. Ex. 12 at ¶¶ 78-79. According to data from Plaintiffs' expert Craig J. McCann, HBC's market share on a Morphine Milligram Equivalent ("MME") and dosage unit basis was [redacted]% and [redacted]%, respectively, for Cuyahoga County and [redacted]% and [redacted]%, respectively, for Summit County.[20]

- Although national demand and DEA quotas for hydrocodone increased dramatically from 2011 to 2015, Giant Eagle's distribution of HCPs peaked in 2011 and decreased year-after-year until October 2014, when Giant Eagle stopped distributing HCPs. *See* Ex. 12 at ¶ 77 & Ex. G; Ex. 11 at 156:3-20; Ex. 23; Ex. 24 at 97:22-98:4 (confirming aggregate production quota history from 2009-2018).

[18] According to the DEA's 30(b)(6) deponent "it was common for legitimate pharmacies to have a ratio of approximately 20 percent of controlled to 80 percent noncontrolled." Ex. 19 at 260:1-22; *see also* Ex. 20 at 453:16–454:8 (explaining that its "a red flag when a pharmacy is ordering, you know, 40, 50 percent of their drugs has controlled substances"). The highest percent of controls to non-controls for any single Giant Eagle pharmacy in the Counties from November 2009 through May 2018 was 13.9 percent, and that was a pharmacy located directly across the street from a hospital. Ex. 12 at ¶ 165 and Ex. H.

[19] Ex. 21 at 48:11-18 ("Q. Do you recall any approach or strategy by Giant Eagle to increase sales of opioids at any time in any party of the company? A. No.").

[20] Ex. 22 (Plaintiffs' Expert Report of Craig J. McCann) at 49 & App. 9, pages 3779, 3775, 3849 & 3845. MME is a conversion factor that measures the relative potency of different opioids so that they can be compared. *Id.* at 49.

Reviewing the components of this integrated system, Giant Eagle's two experts—Sandra Kinsey and Matthew Greimel—concluded that Giant Eagle is, and always has been, compliant with the CSA and its regulations. *See, e.g.*, Ex. 12 at 9 (expert conclusion "k"). Ms. Kinsey and Mr. Greimel have relevant and extensive experience in the pharmaceutical industry and law enforcement, respectively, and, as their reports attest, they reviewed all of the relevant evidence in this case. Plaintiffs have proffered no evidence to the contrary, expert or otherwise.

II. ARGUMENT

A. Plaintiffs cannot establish Giant Eagle did anything wrong.

1. *The Court must dismiss Plaintiffs' negligence claim because Plaintiffs have failed to rebut Giant Eagle's expert evidence.*

To establish "breach" Plaintiffs must show that Giant Eagle fell short of the relevant standard of care. *Ray v. Wal-Mart Stores, Inc.*, 993 N.E.2d 808, 815 (Ohio Ct. App. 2013).[21] In the absence of any expert testimony establishing a clear standard of care, Plaintiffs appear to rely on the CSA and its regulations. However, even if Plaintiffs are relying on federal law to set the standard, they still "must present expert testimony in order to establish that Defendants breached any such standard of care found in the regulations." *Kinn v. HCR Manorcare*, 2011 Ohio Misc. LEXIS 13507, at *5 (Ohio C.P. Nov. 29, 2011); *see also Ramage v. Cent. Ohio Emergency Servs., Inc.*, 592 N.E.2d 828, 834 (Ohio 1992) (reversing trial court because expert testimony on standard of care, breach, and proximate cause were required); *McNeil Pharm. v. Hawkins*, 686 A.2d 567,

[21] A cause of action for negligence requires that Plaintiffs show (1) a duty owed by Giant Eagle to the Plaintiffs; (2) Giant Eagle breached the duty; (3) Plaintiffs suffered cognizable injury; and (4) Giant Eagle was the proximate cause of Plaintiffs injuries. *Menifee v. Ohio Welding Prods., Inc.*, 472 N.E.2d 707, 710 (1984). Beyond failing to establish breach, Plaintiffs cannot show that Giant Eagle had a duty *to the Counties*, as Giant Eagle could not have foreseen the risks and harm likely to occur in the Counties, based on legal prescription-filling activities and its *de minimis* contribution to the opioid market. 70 Ohio Jur. 3d Negligence § 11 (*citing Bailey v. U.S.*, 115 F. Supp. 3d 882, 893 (N.D. Ohio 2015)) (the existence of a duty, "depends on the foreseeability of the injury, and an injury is 'foreseeable' if defendant knew or should have known that [its] act was likely to result in harm to someone."); *see Menifee*, 472 N.E.2d at 710 (in determining whether defendant "should have recognized the risks involved, only those circumstances which they perceived, or should have perceived, at the time of their respective actions should be considered."). Giant Eagle did not owe the Counties any duty to prevent the harm that Plaintiffs allege.

583 (D.C. 1996) (requiring "expert testimony to explain the applicability of statutes where the statute is relied upon as establishing the standard of care"). Plaintiffs' experts make general statements about the CSA and its regulations and opine at length about other defendant's SOM systems, but they do not provide *any* opinion about Giant Eagle's compliance or lack thereof. Further, the facts show that the DEA inspected and audited Giant Eagle's distributions facilities and never found them to be in violation of the CSA.

As noted above, the DEA's regulations are flexible in order to encourage each registrant to design a SOM system that meets the requirements of its specific distribution model and customer base. Ex. 3 at 446:18-447:14. The DEA does not require any single feature or particular format and does not even state a preference between automated or manual systems. *Id.* at 179:22–180:22, 181:23–182:1 (DEA witness testimony that "however they design it, [registrants] need to get the big picture so that they truly know what is their customer doing"). For this reason, the DEA inspects each individual distribution center to look at its business model and ensure that it is "operating a system that can detect a suspicious order." *Id.* at 128:24–130:12.

In all of its inspections and audits, the DEA never cited Giant Eagle for any violation—it never even recommended a material change to Giant Eagle's SOM system. *Cf.* Ex. 3 at 131:15-23 (affirming that the DEA would tell a registrant if, in "either in the pre-registration process or in the audit process the DEA determine[d] that a registrant's system was not adequately detecting suspicious orders"). This is no surprise. As described above, Giant Eagle only distributed to its own pharmacies and, because its self-distribution was integrated with the rest of the company, the monitoring system benefitted from integrated controls at multiple levels of the organization.

Plaintiffs proffered two experts who opine on SOM systems: James Rafalski and Seth Whitelaw. Both experts say *absolutely nothing* about Giant Eagle or its HBC warehouse.[22] Mr. Rafalski provides an overview of the DEA's regulatory framework and then applies that framework to fact specific analyses of (1) four Distributor Defendants; (2) two Pharmacy Chain Defendants; and (3) Seven Manufacturer Defendants.[23] Similarly, Mr. Whitelaw provides an overview of the "Compliance Program Standards," before "measuring [the] compliance effectiveness" of (1) three Distributor Defendants; (2) two Pharmacy Chain Defendants; and (3) one Manufacturer Defendant.[24] The application of the regulations to the unique situation of each of these other defendants emphasizes Mr. Whitelaw's opinion that "the basic regulatory construct for pharmaceuticals… is to provide the industry with 'what' is expected, but not dictate 'how' those expectations are achieved. The 'how' is left to the individual organizations to determine the best methods to comply." Ex. 26 at 23.

Giant Eagle's two proffered experts—Ms. Kinsey and Mr. Greimel—explain "how" Giant Eagle achieved those expectations. Ms. Kinsey and Mr. Greimel analyzed Giant Eagle's SOM systems and concluded that Giant Eagle is, and always has been, compliant with the CSA and its regulations. *See, e.g.*, Ex. 12 at 9 (expert conclusion "k"). Based on her substantial experience as a pharmacy executive and practicing pharmacist, Ms. Kinsey explains how Giant Eagle "complies with all regulations and actively maintains a complex SOM system of integrated controls." *Id.* ¶

[22] Plaintiffs' expert Craig McCann, an economist, analyzes data from HBC in his Report. McCann bases his "analysis" on far-reaching assumptions and admits that what he was "really doing [in his report] is just comparing two datasets," and that his resulting opinions "are really about the data. Not about—about some subject matter conduct by any of the parties." Ex. 25 89:14-15, 92:10-12; 129:6-15 ("I'm just serving as a calculator"). McCann does not base his evaluation of transactions on pharmaceutical practices at Giant Eagle or anywhere else. *See generally*, Ex. 12 at § VI.

[23] Mr. Rafalski analyzed facts specific to: Distributor Defendants Cardinal Health, McKesson Corp., AmerisourceBergen, and Henry Schein, Inc.; Pharmacy Chain Defendants CVS Health and Walgreen Boots Alliance; and Manufacturer Defendants Allergan, Janssen, Mallinckrodt, Purdue Pharma, Endo, Teva, and Insys. Ex. 28 at TOC.

[24] Mr. Whitelaw analyzed facts specific to: Distributor Defendants Cardinal Health, McKesson Corp., and AmerisourceBergen; (2) Pharmacy Chain Defendants CVS Health and Walgreens; and (3) Manufacturer Defendant Mallinckrodt. Ex. 26 at TOC.

138. Similarly, Mr. Greimel, a decorated DEA Agent who worked on dozens of diversion investigations, concludes that Giant Eagle "complied with the DEA's standards in all relevant respects, especially considering that HBC was both a captive self-distributor and only distributed Schedule III-V controlled substances." Ex. 2 at 6-7.

Without any expert testimony from Plaintiffs to rebut Ms. Kinsey and Mr. Greimel, their opinions that Giant Eagle "ha[s] not breached the standard of care… [stand] unrebutted in the trial court." *Skiles v. Bellevue Dev. Corp.*, 2008-Ohio-78, *37 (Jan. 11, 2008 Ct. App.) (affirming summary judgment because defendant's expert opinion evidence "that he had not breached the standard of care for his work stood unrebutted"). As a result, Plaintiffs' "fail[ure] to present competent [or any] expert testimony supporting their claims of negligence," by Giant Eagle is fatal to their case. *See id.*; *see also Montgomery v. Gooding, Huffman, Kelly & Becker*, 163 F. Supp. 2d 831, 836 (N.D. Ohio 2001) (granting summary judgment to defendant law firm in a legal malpractice action because plaintiffs failed to present expert testimony establishing a breach of the standard of care); *Simon v. Drake Const. Co.*, 87 Ohio App. 3d 23, 26 (Ohio App. 1993) ("Once Kekst presented expert testimony, Simon was forced to present expert testimony that Kekst failed to meet the standard of care."); *cf. Kinn*, 2011 Ohio Misc. LEXIS 13507 *4-6 (denying plaintiff summary judgment because, even assuming that the regulations announce a standard of care, plaintiff failed to present expert testimony establishing defendants breached any such standard).[25] For this reason, the Court must dismiss Plaintiffs' negligence claim against Giant Eagle.[26]

[25] *See also, e.g.*, *McNeil Pharm.*, 686 A.2d 567, 583 (D.C. 1996) (holding that "in the face of defense experts who testified that there was no breach of the standard of care, and statutes and regulations which required expert explication," plaintiff was required to present expert testimony concerning the interpretation of the statutes and regulations"); *EQT Prod. Co. v. Vorys, Sater, Seymour & Pease, LLP*, No. 15-146-DLB-EBA, 2018 U.S. Dist. LEXIS 72687, 2018 WL 1996797 (E.D. Ky. Apr. 27, 2018) (granting summary judgment because plaintiff "was required to present expert testimony to establish the standard of care and a breach of that standard of care, and the proffered expert testimony is insufficient").

[26] In depositions, Plaintiffs alleged (1) perceived gaps in Giant Eagle's written policies, (2) defects in Giant Eagle's document retention policies, and (3) violation of the alleged "no ship" requirement. *See, e.g.*, Ex. 10 at 170:10-174:4;

2. Plaintiffs did not, and cannot, point to any evidence of injury (let alone proximate harm) caused by Giant Eagle.

The only evidence Plaintiffs identified that allegedly connects Giant Eagle's self-distribution of pharmaceuticals to *any* harm or damages—over 100 Giant Eagle prescriptions identified by Plaintiffs pursuant to Discover Ruling 5—is also fatally flawed. Not one of the prescriptions is for a medication distributed through Giant Eagle's warehouse distribution system (i.e. HBC or GERXDC).[27]

Plaintiffs initially refused to answer interrogatories about Defendants' prescriptions but, in October, Special Master Cohen ordered Plaintiffs to identify 500 "specific inappropriate opioid prescriptions." Disc. Ruling No. 5, Dkt. No. 1027 (Oct. 6, 2018). Plaintiffs responded to this Order by providing documents listing 7,879 prescriptions; 124 of those prescriptions were filled at Giant Eagle pharmacies.

Giant Eagle's activities as a retail pharmacy are relevant *only* to the extent that they relate to Giant Eagle's activities as a self-distributor of Schedule II opioids or HCPs. *See* Op. and Order at 2, Dkt. No. 1203 (Dec. 19, 2018) ("Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers and dispenser of opioids…the Retail Pharmacies may only be held liable as Distributors.") Therefore, one would expect Plaintiffs would identify prescriptions for medications that Giant Eagle distributed to itself—otherwise the prescriptions

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Ex. 14 at 146:5-147:1, 241:6-242:9; Ex. 1 at 64:19-66:3; Ex. 8 at 171:2-178:2. Leaving aside that these alleged faults cannot carry a cause of action for negligence against Giant Eagle, these arguments are directly refuted by DEA regulations, which do not require a written policy (though it is clear that Giant Eagle did have written policies in 2009 when it began distributing controlled substances, *see e.g.,* Ex. 6), do not require the creation or retention of any of the documents that Plaintiffs allege Giant Eagle should have maintained, and do not require that self-distributors not ship to their own stores before clearing orders of interest. The record also shows that, because Giant Eagle was a self-distributor, it continued to control its product *after* it shipped. Therefore, even if an "order of interest" shipped before investigators cleared it, Giant Eagle was "able to intercept, retrieve, quarantine product all the way up to the time it gets to the store, after it lands at the store, when in transit with the truck." Ex. 8 at 173:15-174:8; *see also* Ex. 9 at 259:25-260:13 ("If something needed to be quarantined and removed from dispensing stock, we had the ability to have our stores pull that aside, if necessary, to prevent it from being dispensed").

[27] Giant Eagle also joins in *Pharmacy Defendants' Motion for Summary Judgment on Causation*, which contains arguments as to why Plaintiffs lack sufficient evidence of causation as to *all* Pharmacy Defendants.

would be completely immaterial to the allegations against Giant Eagle. But not a single prescription from the 124 Plaintiffs identified was a product that Giant Eagle distributed. Instead, the prescriptions are all for medications that Giant Eagle pharmacies ordered from *other* distributors, and which were subject to the monitoring conducted by those other distributors. *See* Ex. 27 at ¶¶ 3, 10-11.

Thus, the *only* "evidence" Plaintiffs identified connecting Giant Eagle to any possible harm in the Counties is actually entirely irrelevant to Plaintiffs' case against Giant Eagle. This leaves Plaintiffs with no evidence that Giant Eagle caused them *any* injury.

B. <u>The Court must dismiss all of Plaintiffs remaining claims on the same bases.</u>

The lack (or failure) of the proffered evidence referenced above also completely obviates Plaintiffs' remaining claims against Giant Eagle. For this reason Giant Eagle is also entitled to summary judgment on Plaintiffs' claims alleging public nuisance (Counts 5 and 6), injury through criminal acts (Count 9), unjust enrichment (Count 10), and punitive damages.

1. The Court must dismiss Plaintiffs' public nuisance claims.

Plaintiffs seek relief for "absolute" public nuisance, which imposes strict liability when there is an interference with a public right through (1) an inherently dangerous activity, (2) intentional culpable conduct, or (3) unlawful conduct. *See Combs v. Baker*, 2001-Ohio-8650, 2001 Ohio App. LEXIS 5335, at *14-16 (Ohio Ct. App. 2001). The undisputed evidence shows that Giant Eagle engaged in none of these activities.[28]

As previously noted, Giant Eagle's self-distribution activities—the only activities that Plaintiffs attack—moved relatively modest amounts of medication from a Giant Eagle warehouse to Giant Eagle pharmacies, where licensed pharmacists dispensed them pursuant to legitimate

[28] Giant Eagle maintains that the Ohio Products Liability Act (the "OPLA") bars Plaintiffs' negligence claims against it as a supplier. Ohio Rev. Code §§ 2307.71(B), 2307.71(A)(13); *see also* Mfg. Memo (Dkt. No. 491-1) at 46-49.

prescriptions. Specific to the Counties, Giant Eagle's market share for distribution of opioids, in MMEs, was less than 1% in each. *See* Ex. 22 at App. 9, p. 3779, 3775, 3849, 3845. This is not an inherently dangerous activity and, to the contrary, is an entirely safe and legal activity.

Putting aside the complete lack of evidence that Giant Eagle engaged in any culpable or illegal conduct (and the unrebutted evidence that Giant Eagle was in compliance with all relevant laws and industry standards), there is no evidence that Giant Eagle's alleged actions interfered with any "public right." Among the almost 8,000 "inappropriate" prescription Plaintiffs identified, not even one involved a medication distributed by Giant Eagle. *See City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 897 F. Supp. 2d 633, 640 (S.D. Ohio 2012) (noting that "even if," the practices alleged by the City were "actionable absolute nuisances, the City must also demonstrate that its damages were proximately caused by those practices").

Finally, both the State of Ohio and the DEA licensed, inspected, and audited Giant Eagle's distribution activities and order monitoring procedures. Courts have found that "part of the *quid pro quo* for the submission to such exacting regulatory oversight is the operator's insulation from liability under a theory of strict liability." *State ex rel. Schoener v. Bd. of Cty. Comm'rs*, 619 N.E.2d 2, 6 (Ohio App. Ct. 1992) (concluding the trial court did not err when it refused to instruct the jury on absolute nuisance). For these reasons, the Court must grant summary judgment on Plaintiffs' nuisance claims against Giant Eagle.[29]

[29] Plaintiffs' statutory nuisance claim asserts that Giant Eagle created a nuisance by violating a law or board of pharmacy rule "controlling the distribution of a drug of abuse." SAC ¶ 979. Plaintiffs rely on empty allegations that Giant Eagle violated Ohio Revised Code §§ 2925.02(A), 4729.01, Ohio Administrative Code 4729-9-12, 4729-9-16, 4729-9-28, 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 to support the claim. SAC ¶¶ 984-86. As noted above, Giant Eagle's has proffered unrebutted expert testimony contradicting these claims and the record contains no evidence to the contrary. Therefore, Plaintiffs' statutory nuisance claim is equally without merit.

2. The Court must dismiss Plaintiffs' injury through criminal acts claim.

To support their injury through criminal acts count, Plaintiffs must show that they were "injured in person or property by a criminal act." Ohio Rev. Code § 2307.60.[30] Plaintiffs support this claim by alleging that Giant Eagle violated Ohio Revised Code § 2925.02(A), which criminalizes "[c]orrupting another with drugs" by "knowingly administer[ing] or furnish[ing]… induce[ing] or cause[ing] another to use a controlled substance with purpose to cause serious physical harm" or drug dependence. Ohio Rev. Code § 2925.02(A)(2).[31]

There is zero evidence that Giant Eagle corrupted anyone with drugs, intended to cause physical harm to anyone, or distributed medication that was wrongfully diverted. Plaintiffs' only proffered "evidence" of "inappropriately" dispensed medication (the 124 prescriptions) is wholly unrelated to Giant Eagle's distribution activities, and thus fails to even *suggest* criminal intent or activity by Giant Eagle. Plaintiffs cannot support any of the elements of Ohio Revised Code § 2925.02(A), compelling the Court to grant summary judgment on Count 9.

3. *The Court must dismiss Plaintiffs' unjust enrichment and punitive damages claims.*

In Ohio, "one is unjustly enriched if the retention of a benefit would be unjust, and one should not be allowed to profit or enrich himself or herself inequitably at another's expense." 18 Ohio Jur. Contracts § 279. Plaintiffs allege that they "conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of harms caused by Defendants' improper distribution practices." Op. and Order (Dkt. No. 1203), Dec. 19, 2018 (quoting SAC).

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[30] Giant Eagle continues to assert that it must be convicted of a crime to be liable under Ohio Revised Code § 2307.60. This question has been certified to the Ohio Supreme Court. Op. and Order (Dkt. No. 1203) at 36. There is no evidence of Giant Eagle's conviction of any crime or criminal provision.

[31] The exception provided in the Code, §2925.02(B) states that the other provisions of Ohio Revised Code § 2925.02(A) do not apply to "wholesalers . . . and other persons whose conduct is in accordance with" state laws governing controlled substances. At all times, Giant Eagle's conduct was pursuant to a valid license, followed state law, and was *bona fide*. *See State v. McCarthy*, 605 N.E.2d 911, 913-14 (Ohio 1992) (criminal intent required to show acts were not *bona fide*).

This claim must fail because no facts connect any costs to the County with Giant Eagle's distributions practices. Plaintiffs' singular effort to draw a connection by identifying "inappropriate prescriptions" (assuming Plaintiffs could connect those prescriptions to costs paid by Plaintiffs), failed. Without such a connection, Plaintiffs cannot show that their payment conferred a benefit on Giant Eagle, and their unjust enrichment claim must fail. *Wright v. City of Dayton*, 814 N.E.2d 514 (Ohio App. 2004).

Finally, without any viable substantive claims, there is no basis for punitive damages. *Miller v. City of Xenia*, 2002-Ohio-1303, 2002 Ohio App. LEXIS 1315, at *9-10 (Ohio Ct. App. Mar. 22, 2002). Further, punitive damages may "be awarded in tort claims only upon a finding of actual malice, fraud, or insult on the part of the defendant." *Terek v. Finkbiner*, No. 3:14 CV 1391, 2015 U.S. Dist. LEXIS 124939, at *6, 2015 WL 5542535 (N.D. Ohio 2015). There is no evidence of any of these factors with regard to Giant Eagle.

III. CONCLUSION

Giant Eagle has proffered two expert opinions showing that its SOM system was both compliant and highly effective at preventing diversion; Plaintiffs have failed to provide any expert opinion rebutting or even challenging these opinions. Plaintiffs identified over 100 Giant Eagle prescriptions that they claimed were "inappropriate"; Giant Eagle has shown that these prescriptions have nothing to do with the claims against Giant Eagle in this litigation.

Plaintiffs' case against Giant Eagle began with a dearth of facts and vague allegations common to all defendants. The evidence that the parties have presented in the ensuing months only confirms that Giant Eagle should never have been in this litigation. In short, before Plaintiffs built their case, it collapsed. The Court should grant summary judgment in favor of Giant Eagle on all counts.

Dated: June 28, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(f)

Pursuant to Local Rule 7.1(f), I hereby certify that this Court has ordered that individual Defendants' summary judge briefs are subject to limit of 18 pages per defendant. *See* Order Regarding Pretrial Motion for "Track One" Trial (Dkt. No. 1653) at 3-4. The foregoing Memorandum of Law is 18 pages in length.

Dated: June 28, 2019

Respectfully submitted,

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